Brief Intervention to Prevent Alcohol Socialization (BIPAS Alcohol)

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
BIPAS Alcohol research study provider intervention

Consent Form Version Date: March 10, 2023
IRB Study # 22-0101
Title of Study: Brief Intervention to Prevent Alcohol Socialization (BIPAS Alcohol)
Principal Investigator: Melissa Gilkey
Principal Investigator Department: Department of Health Behavior
Principal Investigator Phone number: (919) 966-8650
Principal Investigator Email Address: gilkey@email.unc.edu
Funding Source: National Institute of Alcohol Abuse and Alcoholism (NIAAA) [Federal]

Study Contact Telephone Number: (984) 999-1617
Study Contact Email: mpearsall.contractor@rti.org

CONCISE SUMMARY

The purpose of this research is to test the feasibility and effectiveness of an intervention to provide information about early onset alcohol use and negative effects to clinicians and parents of children aged 10-12 years.

Participation will entail receiving text messages up to three times per week for six months. Text messages will include information, resources, and recommendations about early onset alcohol use and negative effects. You will also be asked to complete monthly surveys about the text messages. Your child will also be asked to participate in this study (you may provide your permission on the "parent assent" form) by completing a survey and two interviews.

You are being asked to be in the study because you have experience as a parent or caregiver of a rising 6th grade student. Potential short-term risks associated with participation include slight risk of embarrassment or discomfort in answering questions about your family practices. If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also

may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research is test the feasibility and effectiveness of an intervention to provide information about early onset alcohol use and negative effects to clinicians and parents of children aged 10-12 years.

You are being asked to be in the study because you have experience as a parent or caregiver of a rising 6th grade student.

Are there any reasons you should not be in this study?

You should not be in this study if you are younger than 18 years old, you are not the parent/caregiver of a child aged 10-12 years old, you do not live at least part-time with your child, or you do not own a phone with access to internet and text messaging.

How many people will take part in this study?

A total of approximately 50 parents and 50 children will take part in the parent component of this study.

How long will your part in this study last?

Your participation will last for approximately six months.

What will happen if you take part in the study?

You will receive text messages up to three times per week for six months. Text messages will include information, resources, and recommendations about early onset alcohol use and negative effects. You will also be asked to complete monthly surveys about the text messages.

Your child will also be asked to participate in this study (you may provide your permission on the "parent assent" form) by completing a survey and two interviews.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may benefit by receiving new knowledge about early onset alcohol use.

What are the possible risks or discomforts involved from being in this study?

Potential short-term risks associated with participation include slight risk of embarrassment or discomfort in answering questions about your practices with alcohol in your home.

We do not anticipate immediate or long-range risks associated with participation.

How will information about you be protected?
Every effort will be taken to protect your identity as a participant in this study. You will not be identified in any report or publication of this study or its results. Your name will not appear on any transcripts; instead, you will be given a code number. The list which matches names and code numbers will be kept in a password protected file on a secure server. Audio recordings of interviews will be deleted after they have been transcribed.

Researchers are required by law to report child abuse and neglect to the Director of Social Services in the county where the child resides if it is reported to them by a participant.

We may use de-identified data from this study in future research without additional consent.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. If you wish to do so, please tell a member of the study team and that individual will verbally confirm understanding of your wishes and make a note in study documentation. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
Your family will receive a $70 gift card for participating in this intervention.

If you withdraw from the study before you have completed the intervention, you will not receive the gift card.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the National Institute for Alcohol Abuse and Alcoholism (NIAAA). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If

you have questions about the study (including payments), complaints, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant	Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: March 10, 2023
IRB Study # 22-0101
Title of Study: Brief Intervention to Prevent Alcohol Socialization (BIPAS Alcohol)
Principal Investigator: Melissa Gilkey
Principal Investigator Department: Health Behavior Operations
Principal Investigator Phone number: 919-966-8650
Principal Investigator Email Address: gilkey@email.unc.edu
Funding Source and/or Sponsor: NIH National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Study Contact Telephone Number: 984-999-1617
Study Contact Email: mpearsall.contractor@rti.org

CONCISE SUMMARY

The purpose of this research is to test the feasibility and effectiveness of an intervention to provide information about early onset alcohol use and negative effects to clinicians and parents of children aged 10-12 years.

Your child will be asked to participate in two interviews with our research team about their alcohol knowledge. Your child will also be asked to provide their assent, separately.

Your child is being asked to participate because they are a rising 6th grade student. Potential short-term risks associated with participation include slight risk of embarrassment or discomfort in answering questions about your family practices. If you are interested in learning more about this study, please continue reading below.

What are some general things you and you child should know about research studies?
You are being asked to allow your child to take part in a research study. To join the study is voluntary.
You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.
You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn more about the feasibility and effectiveness of an intervention providing information about early onset alcohol use to parents and clinicians of children aged 10-12 years old.

Are there any reasons your child should not be in this study?
Your child should not be in this study if they are not between the ages of 10-12 years old or if they are being treated for an alcohol use disorder.

How many people will take part in this study?
Approximately 50 children at your child's pediatric clinic and another study clinic will take part in this study.

How long will your child's part in this study last?
Your child will be asked to participate in two interviews, which will each last for 45 minutes or less. The interviews will take place approximately three months apart.

What will happen if your child takes part in the study?
If your child takes part in this study, we will contact you two times over the course of six months to set up an interview for your child. The interviews will take place remotely or in-person at your clinic and will last for 45 minutes or less. We will ask that you are not present during the interview, but the interview will be conducted by a IRB-approved study staff member.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There is little chance your child will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?
There is a slight risk of embarrassment or discomfort about answering questions about your family's experiences. Your child is free not to answer any questions they do not wish to answer or to end the interview at any time.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about your child be protected?

Your child's interview will be audio recorded for transcription. Your child may request to turn off the audio recording at any time during the interview. After the interview has been transcribed, your child's audio recording will be deleted. All interview recordings and notes will be stored on a secure UNC server.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Researchers are required by law to report child abuse and neglect to the Director of Social Services in the county where the child resides if it is reported to them by a participant.

Check the line that best matches your choice:

_____ OK to record me during the study

_____ Not OK to record me during the study

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific

research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if your child is injured by this research?

All research involves a chance that something bad might happen to your child.

If you think your child has been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you and your child should do.

By signing this form, you/your child do not give up your right to seek payment or other rights if your child is harmed as a result of being in this study.

What if you or your child wants to stop before your child's part in the study is complete?
You can withdraw your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because your child failed to follow instructions or because the entire study has been stopped.

If you withdraw your child or your child is withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your child's withdrawal

Will your child receive anything for being in this study?
Your child will receive a $30 gift card for being in this study.

Will it cost you anything for your child to be in this study?
There are no additional costs for your child to participate in this research study.

Who is sponsoring this study?
This research is funded by the National Institute of Alcohol Abuse and Alcoholism. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?
You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, or concerns, contact the researchers listed on the first page of this form**.**

What if there are questions about your child's rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Participant (child)

_____
Signature of Parent

_____
Date

_____
Printed Name of Parent

_____
Signature of Research Team Member Obtaining Permission

_____
Date

_____
Printed Name of Research Team Member Obtaining Permission

_____
Signature of Witness (if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness